

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ENDO PHARMACEUTICALS INC., Plaintiffs, v. ROXANE LABORATORIES, INC., Defendant.	C.A. No. 13-cv-3288-TPG PUBLICLY FILED REDACTED VERSION
ENDO PHARMACEUTICALS INC., Plaintiff, v. RANBAXY LABORATORIES LTD., RANBAXY INC., AND RANBAXY PHARMACEUTICALS INC., Defendants.	C.A. No. 13-cv-04343-TPG C.A. No. 13-cv-08597-TPG

**MEMORANDUM IN SUPPORT OF DEFENDANTS'
MOTION *IN LIMINE* TO EXCLUDE UNQUALIFIED
TESTIMONY OF REZA FASSIHL, PH.D**

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PRELIMINARY STATEMENT

The full scope of opinions proffered by Endo's formulations expert, Reza Fassihi, Ph.D., extends well beyond his area of expertise. For at least two reasons, the Court should exclude testimony for which Fassihi possesses no expertise. First, although Endo proffers him as a pharmaceutical formulations expert, his expert reports contain opinions [REDACTED] [REDACTED]. Any testimony at trial by Fassihi on such issues would not be reliable. Second, Endo has disclosed the opinions of a medical doctor who is expected to testify regarding [REDACTED], rendering duplicative any testimony at trial by Fassihi on [REDACTED].

Fassihi accordingly should be precluded from testifying at trial about [REDACTED] [REDACTED] [REDACTED].

ARGUMENT

The Court should exclude testimony that is admittedly beyond the area of Fassihi's expertise or is cumulative under Rule 403. The use of expert testimony at trial is governed by Federal Rule of Evidence 702. *See R.F.M.A.S., Inc. v. So*, 748 F. Supp. 2d 244, 248; 251-53 (S.D.N.Y. 2010). When evidence is disputed under Rule 702, the proponent of the proffered expert testimony has the burden to demonstrate the testimony's admissibility by a preponderance of the evidence. *Daubert v. Merrell Dow Pharma., Inc.*, 509 U.S. 579, 592-93 (1993). The Court has the authority to screen expert testimony for relevance and reliability. *Id.* at 589. Rule 702 mandates that expert testimony is not reliable where an expert is unqualified to opine on an issue. *See R.F.M.A.S.*, 748 F. Supp. at 248; 268-69. Furthermore, it is procedurally proper to

address the qualifications of an expert in an *in limine* setting. *See S.E.C. v. Tourre*, 950 F. Supp. 2d 666, 674-75 (S.D.N.Y. 2013).

Experts are allowed to testify only in areas within their field of expertise. *Travelers Indem. Co. v. Northrop Grumman Corp.*, 12 CIV 3040 KBF, 2014 WL 464769, *2 (S.D.N.Y. Jan. 28, 2014) (citing *United States v. Tin Yat Chin*, 371 F.3d 31, 40 (2d Cir. 2004) (in determining whether a witness is qualified to render an expert opinion, courts compare the expert's area of expertise with the particular subject matter of the proffered testimony.) *See, e.g., Calisi v. Abbott Labs.*, 11-10671-DJC, 2013 WL 5441355, **8-10 (D. Mass. Sept. 27, 2013) (finding that a pharmacologist was not in the position to opine about how a prescribing medical doctor would have interpreted a prescription label.) Where an expert admits he or she is not skilled in the art of a particular field, courts have found the expert to be unqualified to give an opinion pertaining to that field. *See, e.g., Advanced Tech. Incubator, Inc. v. Sharp Corp.*, No. 5:09-CIV-00135-DF-BB, 2010 WL 1170148, at *5 (E.D. Tex. March 22, 2010) (citing *Sundance, Inc. v. Demonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008)); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1047 (D. Minn. 2007).

In addition, Federal Rule of Evidence 403 permits a court to exclude needlessly cumulative evidence or evidence that would be a waste of the court's time. *Highland Capital Mgmt., L.P. v. Schneider*, 551 F. Supp. 2d 173, 176-77 (S.D.N.Y. 2008) (finding it unnecessary and a waste of time for multiple experts to opine on the same subjects). "[A] trial judge retains a wide latitude to exclude irrelevant, repetitive, or cumulative evidence." *United States v. Holmes*, 44 F.3d 1150, 1157 (2d Cir. 1995). The Court has discretion to exclude cumulative testimony because, by virtue of its repetitiveness, the testimony will not help the fact-finder as required

under Rule 702. *See United States v. Mahaffy*, No. 05CR613(S-3)(ILG), 2007 WL 1213738, *3 (E.D.N.Y. Apr. 24, 2007).

Fassihi, a formulation scientist, should be permitted to testify only as to pharmaceutical formulations and should not be permitted to proffer opinions that fall squarely within [REDACTED]

Fassihi is a professor of biopharmaceutical and industrial pharmacy and an alleged expert in the field of biopharmaceutics and pharmaceutical formulations. (Ex. 1, Fassihi 10/30/14 Roxane Rpt. at ¶ 18; Ex. 2, Fassihi 10/30/14 Ranbaxy Rpt. at ¶ 18 (13-cv-04343); Ex. 3, Fassihi 10/30/14 Ranbaxy Rpt. at ¶ 18 (13-cv-08597); Ex. 4, Fassihi Dep. at 32:10-12.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Fassihi, however, offers opinions in his expert reports relating to topics on which he has no significant training or experience, let alone expertise. Fassihi's expert reports include opinions on issues such as [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Fassihi provides these opinions even though he is not

[REDACTED]

[REDACTED]. Any testimony at trial by Fassihi on such issues would plainly not be reliable.

Pharmaceutics experts such as Fassihi do not concern themselves with product labels and how, if at all, to communicate their contents, suggestions, or instructions to anyone. Specifically, they would not concern themselves with how physicians would instruct patients to take a pharmaceutical composition using Roxane's or Ranbaxy's respective product labels or inserts or how patients would interpret or follow such instructions. Accordingly, Fassihi should not be permitted to opine about whether [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Fassihi also, during his deposition, offered his opinion on [REDACTED]

[REDACTED]

[REDACTED] Because he admittedly [REDACTED]

[REDACTED]

Fassihi should not be permitted to opine on [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Fassihi further opines about [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In

forming his opinions, however, Fassihi directly relies on the opinions in the expert report of Edgar Ross, a medical doctor who has experience in the pharmaceutical treatment of pain. Ross

squarely addressed these points in his expert report and at his deposition. Not only is any testimony at trial by Fassihi on [REDACTED] [REDACTED] unreliable, it would be duplicative of testimony more properly offered by Endo's Ross at trial.

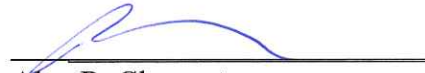
For the above reasons, Fassihi should not be permitted to testify as to certain subject matter of his opinions contained in paragraphs 88-95 of his 10/30/14 expert report to Roxane; paragraphs 90-97 of his 10/30/14 expert report to Ranbaxy (13-cv-04343); paragraphs 90-97 of his 10/30/14 expert report to Ranbaxy (13-cv-08597); paragraphs 345-348 and 350 of his 12/11/14 rebuttal report; and paragraph 9 of his 1/15/15 reply report.

CONCLUSION

For the reasons set forth above, the Court should exclude and/or limit unqualified testimony of Reza Fassihi, Ph.D.

Dated: March 6, 2015

Respectfully Submitted,



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